

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

HARBIGE et al

Atty. Ref.: 604-706; Confirmation No. 1504

Appl. No. 10/756,761

TC/A.U. 1627

Filed: January 14, 2004

Examiner: Kantamneni, Shobha

For: TREATMENT OF NEURODEGENERATIVE CONDITIONS

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION

I, Jacqueline Palace, hereby declare and state that:

1. I am a consultant neurologist and honorary senior lecturer, Radcliffe Hospitals Trust, Oxford, UK.
2. I specialise in multiple sclerosis (MS) (treatment and research studies).
3. I have reviewed Lunardi *et al.*, Neurology, Vol. 48(6), 1997, pp1714-1717, and the Bountra *et al.* patent application (WO0061231).
4. I understand that the assertion is made that a physician treating MS patients would consider Bountra's statement on page 10, lines 3-7 of Bountra *et al.* that:

"A suitable dose is for example 0.1 mg/kg to 30 mg/kg body weight per day calculated as the free base, for example 3 mg/kg to 15 mg/kg. A suitable dose for an adult human is for example in the range of 200mg to 900 mg per day."

5. As a physician having extensive knowledge and experience of MS, I do not agree that patients should be prescribed lamotrigine at doses as high as 900 mg. I base this statement on my review of the doses tolerated in Dr Kapoor's recent lamotrigine trial in secondary progressive MS, where the highest tolerated dose was 300 mg (average only 78 mg) in this population. Indeed, the protocol stated a maximum dose of 400 mg, and I note that this was the maximum dose in the Lunardi study.

I declare that all statements herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.



Jackie Palace

23 3 2010

Date